K083148
1/3

510(k) Summary

NOV - 7 2008

Company Name:	BIO PROTECH, INC. 1720-26, Taejang 2 – Dong, Wonju Woonju-Si, Gangwon-Do Republic of South Korea
Company Address	1720-26, Taejang 2 – Dong, Wonju Woonju-Si, Gangwon-Do Republic of South Korea
Contact Person:	Mr. Kevin Han 17962 Sky Park Circle Suite G Irvine, CA 92614 Phone: 310-515-1799

Summary Preparation Date: June 30, 2008

Trade Name: Telectrode Wet-gel ECG Electrodes

Common Name: Disposable ECG monitoring electrode

Classification Name: Electrocardiograph electrode

Predicate Device Identification:
21 CFR 870.2360
Product Code: DRX
Device Class: Class II

807.92(a)(3)
Legally Marketed Equivalent Device:

Company	*Product*	*510(k) #*
Leonhard Lang Co.	Skintact ECG Electrodes	K982521

807.92(a)(4)

DESCRIPTION:
TELECTRODE Wet gel ECG Electrodes are a single use, self-adhesive, non-sterile, disposable ECG electrode that is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. The sensor is made of ABS plastic that has a Silver / Silver Chloride coating. The lead wire, cable and processor are not included with this device so the type of leadwire, cable and connector are not applicable.

807.92(a)(5)

INTENDED USE:
TELECTRODE Wet gel ECG Electrodes are used to record the following ECGs from a patient: Resting ECG, Exercise ECG and/or ambulatory (Holter) monitoring.

The intended patient population can be adult and pediatric, while the environment of use can be hospital (or clinic), ambulance, or daily use environment (for Holter monitoring).

807.92(a)(6)

Predicate Product Comparison Table:

Parameters		BIOPROTECH Wet-gel ECG electrodes	Predicate Device (Skintact ECG electrodes / S&W electrodes)
510(k) number		Pending	**K982521**
Indications for Use		TELECTRODE Wet gel ECG Electrodes are used to record the following ECGs from a patient: Resting ECG, Exercise ECG and/or ambulatory (Holter) monitoring. The intended patient population can be adult and pediatric, while the environment of use can be hospital (or clinic), ambulance, or daily use environment (for Holter monitoring).	Skintact ECG electrodes are intended for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician.
Target patient population		General [Adult, Pediatric]	General
Intended Use		General [Hospital, Clinic, ambulance, daily use for monitoring]	General
Material Used	Stud	Yes	Yes
	Sticker	Yes	Yes
	Pad	Yes	Yes
	Sensor	Yes	Yes
	Gel	Yes	Yes
	Liner	Yes	Yes
Sterile/Non-sterile		Non-sterile	Non-sterile
ANSI/AAMI EC-12		Pass	Pass
Biocompatibility Tests		ISO 10993-1	ISO 10993-1

Shelf life	Ensures 24 month shelf life	Ensures 24 month shelf life

Substantial Equivalence Discussion
Based on the above predicate product comparison Bio Protech has concluded that no new issues concerning safety and effectiveness are raised in this 510(k) submission. Both products passed the ANSI/AAMI EC-12 tests and both have met the ISO 10993 criteria for biocompatibility.

807.92(b)
SAFETY and EFFECTIVENESS
The electrical performance of Telectrode Wet-gel ECG Electrodes meets the requirements of the voluntary standard ANSI/AAMI EC12 2000.

BIOCOMPATIBILITY
The biological safety of Telectrode Wet-gel ECG Electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The tests were selected on the basis of ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Guidance on selection of test".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

Bio Protech, Inc.
c/o Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K083148
Trade/Device Name: Telectrode Wet-gel ECG Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: October 22, 2008
Received: October 24, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083148

Device Name: Telectrode Wet-gel ECG Electrodes

Indications for Use:

TELECTRODE Wet gel ECG Electrodes are used to record the following ECGs from a patient: Resting ECG, Exercise ECG and/or ambulatory (Holter) monitoring.

The intended patient population can be adult and pediatric, while the environment of use can be hospital (or clinic), ambulance, or daily use environment (for Holter monitoring).

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Y. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083148